UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079

"Track 3 Cases"

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

PHARMACY DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS SECOND AMENDED COMPLAINT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

SUMMARY OF ARGUMENT

The Counties insist they can proceed with their dispensing-related claims even without alleging or proving the "improper dispensing of individual prescriptions" because, in their view, the Controlled Substances Act ("CSA") requires pharmacies to implement corporate-level systems to analyze chain-wide data for signs of wrongdoing by prescribing doctors. *See* Doc. 3366 ("Opp.") at 10, 20–26. This argument fails for at least four reasons. First, Ohio Rev. Code § 4729.35 limits the Counties' public-nuisance remedies to injunctive relief. Second, the CSA does not impose any such requirement, and the Counties fail to present a shred of authority to the contrary. Third, the Counties' claim does not fit within the elements of Ohio's absolute public nuisance doctrine. Finally, the medical judgment of prescribing physicians breaks the causal chain.

The Counties are inviting a disruptive rewriting of the law governing pharmacy practice. They ask the Court to impose a new legal duty on pharmacies to conduct corporate-level data analysis on records of past prescriptions and to use that analysis to reject future prescriptions. Because such a duty would be unprecedented, no existing statute or regulation at the state or federal level would guide pharmacies as to how to proceed. Among many other problems, pharmacies will have no guidance regarding whether or how to use that data to override a contrary professional judgment made by a pharmacist when a patient hands him or her a new prescription. The American Medical Association and several state pharmacy and medical boards have opposed voluntary efforts by pharmacies to impose data-driven dispensing policies that go "beyond a pharmacist's corresponding responsibility,"[1] arguing, in part, that such policies

[1] *E.g.*, Letter from James L. Madara, Exec. VP & CEO, Am. Med. Ass'n, to Paul Beahm, SVP, Health & Wellness Ops., Walmart, Inc. (Oct. 3, 2018), https://searchlf.ama-assn.org/

impermissibly interfere with medical practice. What the Counties propose would only magnify such disputes. The Court should reject the Counties' attempt to use a common law public nuisance claim to rewrite the law and interfere with federal and state regulation of controlled-substance dispensing.[2]

ARGUMENT

I. Ohio Law Does Not Permit a Common Law Public Nuisance Claim Based on a Pharmacy's Alleged Failure to Detect and Prevent Diversion of Drugs of Abuse.

The Counties acknowledge that, although Ohio Rev. Code § 4729.35 provides a public nuisance cause of action for failure to detect and prevent diversion of drugs of abuse, it limits any remedy to injunctive relief. Opp. 2. Yet they argue that they can seek broader remedies, not authorized by that provision, because the statute does not state that "other equitable and common law claims for public nuisance or their corresponding forms of relief" have been abrogated. *Id.*

This argument fails. The "rule of statutory construction" that they invoke, Opp. 5–6, applies only to the repeal of "settled rules of the common law" when the statute in question is tangential to the rule of common law. *State ex rel. Morris v. Sullivan*, 90 N.E. 146, para. 3 of syllabus (Ohio 1909).[3] Here, however, the Counties could not have brought their public

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undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-10-3-Letter-to-Walmart-FINAL.pdf.

[2] CVS Health Corporation and Rite Aid Corporation separately have filed motions to dismiss for lack of personal jurisdiction. They join this reply subject to and without waiving their jurisdictional position.

[3] The Counties' only support for broader applicability of the rule is a case that was overturned by legislation. *See Carrel v. Allied Prods. Corp.*, 677 N.E.2d 795 (Ohio 1997); *see also Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 920 & n.6 (N.D. Ohio 2009) (rejecting reliance on *Carrel* and observing that the dissent in *Carrel* "makes a strong argument that based upon earlier Ohio Supreme Court precedents (which the majority did not distinguish or overrule) the rule of statutory construction applicable [in the context of an enactment not tangential to a rule of common law] is considerably less exacting than the standard articulated by the majority"). To the extent that the Court finds Ohio law unsettled as to which rule of construction

nuisance claim in the absence of comprehensive laws defining and regulating drugs of abuse. Indeed, their claim expressly depends on the existence of the regulatory scheme governing prescription opioid medications and other controlled substances. *See, e.g.*, Opp. 7 (characterizing their claim as seeking abatement and damages for "violations of the controlled drug laws [that] create a significant and unreasonable interference with a public right"); Am. Compl. ¶¶ 556, 559–60 (invoking Ohio regulations). The essential building blocks of the Counties' theory—"diversion" of "controlled substances"—have no meaning at common law.[4] The General Assembly had no reason to declare that it was abrogating the common-law form of the Counties' claims because such claims never existed in the first place.

Additionally, there is nothing tangential about § 4729.35: It directly addresses what remedies are available for a public nuisance action based on the failure to detect and prevent the diversion of drugs of abuse. The General Assembly clearly intended to provide a comprehensive regulatory and remedial scheme governing the dispensing and distribution of controlled substances that, among its enforcement mechanisms, limits public nuisance liability to the relief permitted under § 4729.35. *See* Doc. 3340-1 ("Mot.") 7–11. The Counties are barred from seeking to enforce this comprehensive regulatory regime through an incompatible common law claim. *See Thompson v. Ford*, 128 N.E.2d 111, 115–16 (Ohio 1955) (comprehensive legislation "is indicative of a legislative intent that the statute should totally supersede and replace the common law dealing with the matter") (citing 3 Sutherland Statutory Construction § 5305 (3d ed.)); *see also Delaware v. Purdue Pharma L.P.*, No. N18C-01-223, 2019 WL 446382, at *11

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should apply to § 4729.35, the Court should certify the question to the Ohio Supreme Court. *See Pennington v. State Farm Mut. Auto. Ins. Co.*, 553 F.3d 447, 449–50 (6th Cir. 2009).

[4] Indeed, the Counties themselves acknowledge that nearly all of R.C. Chapter 4729 has "no counterpart in the common law." Opp. 9.

(Del. Sup. Ct. Feb. 4, 2019). The Counties seek to cabin *Thompson* to standards of care, Opp. 8, but offer no justification for doing so; the Court should reject that unprincipled distinction. In *Thompson*, the Ohio Supreme Court articulated a general principle of statutory construction squarely applicable to the General Assembly's comprehensive regulatory scheme governing controlled substances.[5]

The Counties cannot have it both ways, purporting to base their claims on statutory law regulating the dispensing and distribution of prescription opioid medications while seeking to circumvent that very regime by pursuing a remedy it does not permit. The Counties hope the Court will ignore that the limits imposed by § 4729.35 serve the legislative purpose of striking a balance between making medications available to patients who need them and controlling against their abuse—a balance that could easily be upset. *See* Mot. 12–13. If Ohio courts have not had occasion to hold that § 4729.35 bars the remedies the Counties seek, *see* Opp. 5, it only goes to show that the Counties' overreaching theory is unprecedented. Indeed, the Counties can point to no example of any Ohio court *condoning* a public nuisance claim seeking remedies beyond injunctive relief based on an alleged failure to prevent diversion of controlled substances.[6]

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[5] The Counties' attempt to distinguish *Peters Family Farm, Inc. v. Sav. Bank*, No. 10CA2, 2011 WL 497476, at *3 (Ohio Ct. App. Jan. 28, 2011), and other cases concerning the Uniform Commercial Code's displacement of certain common law claims is unsupported by anything more than the Counties' say-so and an isolated dictionary definition. *See* Opp. 8–9 & n.10. Whether the General Assembly "has codified the law on a subject," *Amzee Corp. v. Comerica Bank-Midwest*, No. 01AP-465, 2002 WL 1012998, at *9 (Ohio Ct. App. May 21, 2002) (citation omitted), does not depend on whether prior existing common law is carried through into the codified law—it just means that the law on a certain subject (here, the dispensing and distribution of certain drugs) has been comprehensively and systematically formulated. *See Amzee*, 2002 WL 1012998, at *9 (recognizing that "the UCC has set forth liabilities and responsibilities that are different than existed at common law").

[6] Nor, for that matter, can they provide any example of Ohio courts permitting a public nuisance claim seeking remedies beyond injunctive relief for the unlicensed practice of medicine, chiropractic, or acupuncture. *See* Opp. 9.

The Counties' attempt to tie the fate of their unprecedented claims to the fate of all "common law causes of action related to the conduct of . . . occupations and professions (e.g., medical malpractice actions)," Opp. 9, is absurd. The only claims at issue here are public nuisance claims based on an alleged unlawful failure to detect and prevent the diversion of drugs of abuse and seeking remedies beyond injunctive relief, in plain derogation of § 4729.35. Because Ohio law does not permit them, the Court must dismiss the Counties' common law public nuisance claims.

II. The Counties Have Not Identified Any Unlawful Dispensing Conduct.

The Counties' dispensing-related claims are also based on an untenable understanding of the CSA. They ask the Court to ignore crucial differences between the regulatory regimes governing *distribution* and *dispensing*, and to invent "CSA duties" that simply do not exist. The Court should reject the Counties' misrepresentation of the scope of the regulations implementing the CSA—interpretations endorsed by no court or regulator—and their unfounded and unworkable analogy to the obligations that, the Court has held, fall on distributors.

A. The CSA Does Not Require a System to Detect and Guard Against the Filling of "Suspicious" Prescriptions.

Without support from any case law or even DEA guidance, the Counties imagine that 21 C.F.R. § 1301.71(a) makes it "a violation of the statutory and regulatory scheme" that they can prove without any "requirement of 'knowledge' of any kind" or even the need "to identify particular prescriptions that were improperly filled" if a registrant Defendant fails to "have in place procedures to prevent the filling of suspicious prescriptions without proper investigation." Opp. 14, 20–21. They are mistaken. For one thing, CSA regulations elsewhere provide that any controlled substance prescription is to be filled only at the discretion of a trained and licensed professional pharmacist, who has a responsibility to guard against illegitimate prescriptions. 21

C.F.R. §§ 1306.04(a) & 1306.06. And, crucially, § 1301.71(a) cannot be the basis of the dispensing-related CSA violation that the Counties assert.[7] The Counties' analogy to the Court's holdings in the *distribution* context fails because, with respect to *dispensing* pharmacies, neither § 1301.71(a) nor any other regulation requires a "system" for monitoring prescriptions and disclosing "suspicious orders of controlled substances," *id.* § 1301.74(b).

Section 1301.71(a) provides that, "to determine whether a registrant has provided effective controls against diversion," DEA "shall use the security requirements set forth in §§ 1301.72–1301.76 as standards." The security requirements set forth in §§ 1301.72–1301.76, in turn, provide for one set of "controls" for "non-practitioners" (manufacturer- and distributor-registrants) and another for "practitioners" (a category that includes pharmacy-registrants, *see* 21 U.S.C. § 802(21)). Among the "controls" required for non-practitioners, this Court has held, is that "[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b); *see* Doc. 2483 at 15. No equivalent monitoring requirement applies to practitioners, such as pharmacies. *See* 21 C.F.R. §§ 1301.75–1301.76 (delineating the "controls" required for practitioners).[8] DEA knew perfectly well how to tell registrants to "design and operate a system"; its contemporaneous decision *not* to extend such a requirement to pharmacy-registrants cannot be disregarded. *See, e.g.*, *Keene Corp. v. United* States, 508 U.S. 200, 208 (1993) ("Where . . . particular language [is included] in one section . . . but omit[ted] . . . in another, it is generally presumed that [the drafter] acts

[7] The Counties rightly do not argue that the text of the CSA itself imposes any requirement that pharmacy-registrants maintain effective controls against diversion. Opp. 12.

[8] These include physical security controls and other controls against theft or loss of controlled substances. The Counties do not allege that any Pharmacy Defendant failed to comply with these requirements.

intentionally and purposely in the disparate inclusion or exclusion."); *Iselin v. United States*, 270 U.S. 245, 251 (1926) ("To supply omissions transcends the judicial function.").

The absence of any equivalent obligation on the part of pharmacies is evident not only from the text of the regulations but also from past DEA enforcement actions, which have alleged that pharmacies failed to "maintain effective controls against diversion and theft" only when the pharmacy had deficient in-store security controls. *See ChipRX, L.L.C. d/b/a/ City Center Pharmacy*, 82 Fed. Reg. 51,433-02, 51,434 (DEA Nov. 6, 2017). The Counties cannot cite a single example of any pharmacy anywhere being required to adopt anything like the policies, procedures, and systems they imagine were required here, much less being found deficient for not having done so. Indeed, the Counties cannot cite even a single case stating that such requirements exist—whether under § 1301.71(a) or otherwise. Nor do they even cite a Dear Registrant letter or other regulatory guidance addressing such a purported requirement. The Counties' reading of the regulation is completely without precedent, invented out of whole cloth.

This glaring gap in the Counties' authority is unsurprising. As Pharmacy Defendants have explained, the obligation to evaluate prescriptions resides exclusively with the individual pharmacist presented with the prescription. Mot. 17–20. When the Counties urge that "procedures to prevent the filling of suspicious prescriptions without proper investigation" are "the essence of effective controls against diversion," what they are describing already exists as the *professional practice of pharmacists*, as codified in the CSA and its Ohio analog. Pharmacists are trained professionals obligated to exercise a "corresponding responsibility" for guarding against illegitimate prescriptions—a responsibility that they are uniquely authorized to discharge. *See* 21 C.F.R. § 1306.04(a); Mot. 15 (describing how the practice of pharmacy under Ohio law includes "[p]erforming drug utilization reviews" and other "pharmacist care requiring

specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences" (quoting Ohio Rev. Code § 4729.01(B)). The Counties do not deny that Ohio law expressly forbids Pharmacy Defendants from assessing the validity of prescriptions. *Id.* That responsibility rests with pharmacists. And the Counties have disavowed any claim that any Pharmacy Defendant's pharmacist did not comply with the responsibility to guard against illegitimate prescriptions. *See infra* p. 9.

The upshot of these differences between distribution and dispensing (where, unlike with distribution, there is no suspicious order monitoring requirement and controlled substances are dispensed only upon the professional judgment of a pharmacist) is that the Court's prior holdings on the scope of distributor duties under the CSA and its implementing regulations do not translate to the dispensing context, *see* Opp. 15. The Court's holding that distributors have a duty not to ship a suspicious order absent a due diligence investigation—though not derived from the text of 21 C.F.R. § 1301.74(b)—cannot be divorced from the fact that distributors (unlike pharmacies) are charged with maintaining a system to identify "suspicious orders" in the first place. Doc. 2483 at 16–17. There simply is no legal or logical basis to find that that the phrase "effective controls against diversion"—without more—contains an implicit requirement that pharmacy-registrants devise a system to detect potential patterns of allegedly suspicious activity among patients and prevent the filling of facially legitimate prescriptions, when DEA, despite expressly imposing a "suspicious order" monitoring requirement on distributor-registrants, has imposed no such requirement for pharmacy-registrants. Rather, DEA has imposed a requirement on trained and licensed pharmacists, exercising their professional judgment, to refuse to knowingly fill any illegitimate prescription.

B. The Counties Have Not Alleged Any Unlawful Dispensing in Violation of 21 C.F.R. § 1306.04.

The Counties cannot salvage their dispensing theory by pivoting to 21 C.F.R. § 1306.04. As an initial matter, the Counties disclaim any theory of vicarious liability based on unlawful dispensing by Pharmacy Defendants' pharmacists. *See* Opp. 22 n.22. Rightly so, since they have not identified a single instance of any pharmacist employed by any Pharmacy Defendant knowingly filling a prescription written without a legitimate medical purpose in either County (or elsewhere in Ohio, for that matter). *See* Mot. 20–23. While the Counties treat this disavowal as insignificant, it means they can find no support in any of the many decisions they cite holding pharmacies *vicariously* responsible for pharmacists' violations of their corresponding responsibility, *see* Opp. 10–11, 16 & n.18. *See, e.g.*, *Medicine Shoppe-Jonesborough v. DEA*, 300 F. App'x 409, 412–13 (6th Cir. 2008); *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043-01, 30,043–44 (DEA July 24, 1990); *E. Main Street Pharmacy*, 75 Fed. Reg. 66,149-01, 66,149 (DEA Oct. 27, 2010).[9]

Contrary to the Counties' unsupported suggestion, 21 C.F.R. §§ 1306.03 & 1306.04 do not impose a duty to "ensure that only legitimate prescriptions are filled." Opp. 12. As the Motion explained, in addition to defining and assigning the "corresponding responsibility" for proper dispensing solely to the individual pharmacist presented with a prescription, 21 C.F.R. § 1306.04(a) makes clear that it prohibits only the filling of one or more specific prescriptions that the defendant *knows* were not issued for a legitimate medical purpose. *See, e.g.*, *United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1186–87, 1189 (E.D. Ky.

[9] These decisions show that corporate entities *can* be subject to DEA discipline for improper dispensing in certain circumstances—and thus provide one obvious answer to the Counties' fretting about entities "bear[ing] no responsibility for their dispensing activity," *see* Opp. 18–19.

2017) (defendant's corporate officers specifically knew that a doctor it employed habitually issued certain controlled substance prescriptions outside the course of professional treatment, and that its pharmacists were filling those prescriptions).[10]

The Counties have not alleged and do not intend to prove that any prescription filled by a pharmacist employed by any of the Pharmacy Defendants was, in fact, illegitimate. *See* Opp. 21. And without establishing any underlying illegitimate prescriptions that were filled, they cannot be heard to argue that *any* person knew that any prescription was illegitimate, as required to establish a violation of § 1306.04(a).

The Counties' unprecedented argument that the Pharmacy Defendants should have devised ways to probe their aggregate dispensing data to uncover past indicia of suspicious prescribers or customers is, at most, an allegation of negligence, not willful blindness. Willful blindness requires proof that the defendant (1) "subjectively believe[s] that there is a high probability that [the relevant] fact exists"—that is, that a specific prescription is illegitimate, and (2) "take[s] deliberate actions to avoid learning of that fact" before filling the prescription. *See,*

[10] *See also United States v. City Pharmacy, LLC*, No. 3:16-cv-24, 2016 WL 9045859, at *1–3 (N.D. W. Va. Dec. 19, 2016) (declining to dismiss a civil enforcement action against an individual non-pharmacist owner of a pharmacy that allegedly was *intentionally* used as a front for the owner and his family members to fill illegitimate prescriptions for controlled substances); *Bob's Pharmacy & Diabetic Supplies*, 74 Fed. Reg. 19,599-03, 19,602 (DEA Apr. 29, 2009) (revoking pharmacy registration based on finding that pharmacy, which was owned by a sole proprietor, "was engaged in a criminal scheme to divert controlled substances"); *United Prescription Servs., Inc.*, 72 Fed. Reg. 50,397-01, 50,398 (DEA Aug. 31, 2007) (revoking pharmacy registration where internet pharmacy, which was owned by an individual who also controlled a related internet prescribing site, filled prescriptions that it "knew . . . were invalid"; among other things, it knew that the prescribers neither conducted a physical examination of the patient nor consulted with any medical professional who had). It is revealing that the Counties highlight *United Prescription Services* as "especially instructive." Opp. 19. The egregious scheme described in that case illustrates the specificity and level of knowledge of certain illegitimate prescriptions being filled—far beyond what the Counties allege here—needed to establish that a corporation was directly responsible for the dispensing of controlled substances in violation of § 1306.04(a).

e.g., *Superior Pharmacy*, 81 Fed. Reg. 31,310-01, 31,335 (DEA May 18, 2016) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011)). The Counties allege nothing of the sort.

The Counties have made it clear that they do *not* allege that there were patent signs of illegitimacy when certain prescriptions were presented, but rather that there were latent signals that could be uncovered after the fact, *only* by analyzing aggregate dispensing data. *See* Opp. 19 ("[A]s alleged in the Complaints, it is Defendants, and not any individual pharmacists, that have the data needed to detect patterns of diversion.").[11] By contrast, cases in which pharmacists (or pharmacy-registrants by vicarious liability) have been deemed willfully blind all involve obvious indicia, apparent at the time the prescriptions were presented, that specific prescriptions were not written for a legitimate medical purpose. For example, in *Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79,188-01 (DEA Nov. 10, 2016), the Administrator upheld the

[11] At times, the Counties suggest that the aggregate volume of opioid medications dispensed could have been enough of an indicator of diversion to trigger a sleuthing obligation on the part of Pharmacy Defendants. Opp. 25. But DEA has recognized that "aggregate numbers and relative aggregate numbers of controlled substance prescriptions dispensed . . . do not constitute relevant evidence" of unlawful dispensing "absent a nexus to a red flag of diversion"—that is, an indication that might give a pharmacist reason to suspect that a specific prescription was not legitimate. Order on Hearing Scope & Gov't Mots. Regarding Resps.' Experts at 8, *Holiday CVS, L.L.C.*, Dkt. No. 12-37 & 12-38 (DEA ALJ Apr. 13, 2012), Ex. A; *see also* 21 U.S.C. § 826 (DEA sets quotas on prescription opioids to provide for estimated needs). Indeed, DEA itself "recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the course of professional practice." DEA, Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,721 (Sept. 6, 2006). The Counties also suggest that enforcement proceedings against certain Pharmacy Defendants in other jurisdictions similarly could support a finding of willful blindness, Opp. 25–26, but enforcement actions involving pharmacists filling particular prescriptions outside Ohio could not have put any Pharmacy Defendant on notice of illegitimate prescriptions being filled at other times by other pharmacists inside Ohio. The trademark infringement cases the Counties cite, *see* Opp. 23 (citing *Moroccanoil, Inc. v. Groupon, Inc.*, 278 F. Supp. 3d 1157, 1164–65 (C.D. Cal. 2017), and *Louis Vuitton Malletier & Oakley, Inc. v. Veit*, 211 F. Supp. 2d 567, 583 (E.D. Pa. 2002)), are inapt, as they concerned companies notified of precisely the unlawful conduct they continued.

Administrative Law Judge's finding that the pharmacy's pharmacists had dispensed several dozen specific prescriptions with willful blindness based on unrebutted testimony that those prescriptions were associated with apparent "red flags." *Id.* at 79,188, 79,204, 79,210, 79,218–19. Likewise, in *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043-01 (DEA July 24, 1990), the managing pharmacist was found to have acted with willful blindness when he filled prescriptions for controlled substances under circumstances where "there is no question that a conscientious pharmacist would have been suspicious of these prescriptions and would have refused to fill them." *Id.* at 30,044. Without allegations that any specific prescriptions were filled despite knowledge (or willful blindness to the fact) that they lacked a legitimate medical purpose or were issued outside the usual course of professional practice, the Counties have failed to plead unlawful dispensing in violation of the CSA.

In sum, the Opposition confirms that neither the CSA, its implementing regulations, nor corresponding Ohio statutes and regulations impose the duties the Counties imagine.[12] The Court should decline the Counties' invitation to rewrite the regulatory regime governing dispensing and dismiss their claims to the extent that they seek to establish liability based on unlawful dispensing conduct.

[12] These made-up duties include duties (1) to "analyze [dispensing] data and store level information" for indicators of potential diversion, Am. Compl. ¶ 109; (2) to implement or refrain from implementing particular "policies" for compensating or training pharmacist employees, *see, e.g.*, *id.* ¶¶ 85, 209, 260-62, 316–17, 377; (3) to provide additional training in dispensing for pharmacists, *id.* ¶ 82; (4) to "use data" to identify doctors writing suspicious volumes of prescriptions or to avoid filling prescriptions, *id.* ¶¶ 211, 289, 388; (5) to conduct specific analyses of prescription sales, *id.* ¶ 149; or (6) to conduct "internal or external reviews" of pharmacy sales, *id.* ¶ 83.

III. The Counties' Challenge to Pharmacy Defendants' Corporate Procedures Does Not Fit Within Ohio's Absolute Public Nuisance Doctrine.

As the Motion explained, the Counties' claim—that Pharmacy Defendants should have adopted additional precautions to prevent diversion—fundamentally sounds in negligence; yet the Counties have deliberately avoided pleading a negligence-based qualified nuisance claim. *See* Mot. 23–26. While the Counties attempt to argue that their claims are about something more than negligence, *see* Opp. 26–31, in truth they still pursue what is at heart a qualified nuisance claim and have failed to state a claim under Ohio's absolute public nuisance doctrine.

The Counties assert that they have pled a claim for unlawful conduct; specifically, for violations of the CSA and implementing regulations. *See* Opp. 26–27. This argument fails for the reasons set forth in Part II, *supra*, as neither the CSA nor DEA's regulations impose any obligation to implement the corporate-level procedures the Counties are advocating. It also fails even if one accepts the Counties' interpretation of the CSA, because Ohio courts have made clear that a claim for absolute public nuisance must be based on a violation of a statute that "commands or prohibits the doing of a specific act." *Natale v. Everflow E., Inc.*, 2011-Ohio-4304, ¶ 37. Where a statute merely "sets forth a rule of conduct in general or abstract terms," liability turns on whether the defendant has acted with "due care as exercised by a reasonably prudent person under the circumstances," and the claim remains at heart a claim for qualified nuisance. *See id.*; *see also Taylor v. City of Cincinnati*, 55 N.E.2d 724, 733 (Ohio 1944) (holding that claim based on alleged violation of a statute setting forth "a general rule of conduct" was a claim for qualified nuisance). Because the Counties do not cite any law that specifically and expressly requires the types of policies, procedures, and systems they claim Pharmacy Defendants should have implemented, this case does not involve the type of per se statutory violation that can support an absolute nuisance claim.

The Counties also contend that they have stated a claim for an intentional absolute nuisance, *see* Opp. 27–31, and that this claim does not require proof "that a wrong or the existence of a nuisance was intended," *id.* at 27. This is belied by the Counties' own cited cases, which make clear that an absolute public nuisance requires proof of intent that the defendant "intended to bring about the conditions which are in fact found to be a nuisance." *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863 (N.D. Ohio 2017). Here, the mere dispensing of prescription medications cannot constitute such a "condition" because that conduct was licensed and authorized under the CSA.[13] The Counties' allegation that Pharmacy Defendants should have taken greater care when engaged in that conduct is plainly a claim for negligence.

The Counties' rhetoric cannot transform their negligence claim into one for intentional misconduct. The Counties assert that Pharmacy Defendants supposedly "knew diversion was occurring but deliberately chose to do nothing to prevent it." Opp. 29. But Pharmacy Defendants cannot be liable merely because the Counties allege that they were aware that opioids are subject to abuse. *See* 21 U.S.C. § 801 (despite harms resulting from diversion, controlled substances are "necessary to maintain the health and general welfare of the American people"). Putting aside the Counties' hyperbole, the Amended Complaint does not actually allege that Pharmacy Defendants did "nothing" to prevent diversion; rather, it alleges that they "failed to put in place *effective* policies and procedures." Am. Compl. ¶ 83 (emphasis added). That claim—that Pharmacy Defendants' policies and procedures were not effective—sounds in negligence.

[13] The Counties argue in a footnote that conduct can constitute a per se nuisance even if it is licensed and regulated, arguing that contrary cases should be limited to the "specific context of nuisance claims against solid waste disposal facilities." Opp. 28 n.23. They offer no justification for that unprincipled distinction, however, which would subject broad swaths of lawful conduct to per se liability.

The Counties offer a number of contrary arguments, but all fail. The Counties allege that Pharmacy Defendants "knew" that opioids have "a high potential for abuse," Opp. 28 (marks omitted), but under that theory every distributor of Schedule II controlled substances would be deemed to have engaged in creating an intentional nuisance. The Counties allege that DEA sanctioned certain pharmacies in certain states, *see id.* at 30, but the fact that *some* pharmacies were sanctioned outside of Ohio hardly establishes that any Ohio pharmacy was engaged in a per se nuisance.[14] The Counties also assert that Pharmacy Defendants should have known the overall volume of opioids was greater than "necessary for legitimate medical uses," *id.* at 29, but, even assuming Pharmacy Defendants had the necessary expertise to second-guess the prevailing medical standard of care, Pharmacy Defendants could not cut that overall volume without identifying specific prescriptions that could not be filled. Ultimately, then, the Counties argue that Pharmacy Defendants acted intentionally because they "had extensive distribution and dispensing data" that *could have* been used to identify such prescriptions, *id.*, but the Counties' own allegations make clear that data was meaningless unless subjected to rigorous analysis. *See*, *e.g.*, Am. Compl. ¶ 151. These arguments bring the case back full circle to the Counties' claim that Pharmacy Defendants should have designed and implemented more effective systems to make better use of their data—which, again, is at best a negligence claim.

IV. The Role of Doctors as Learned Intermediaries Bars Any Finding of Proximate Causation as a Matter of Law.

Finally, the Motion explained that the Counties' claims fail for lack of proximate cause, because, under the learned intermediary doctrine, the prescribing decisions of doctors break the

[14] The Counties also say that intent can be inferred from lobbying efforts allegedly aimed at defeating more extensive regulation. *See* Opp. 31. Even imagining the First Amendment allowed that inference (it does not), lobbying aimed at *limiting* regulation hardly supports an inference of awareness that *more* regulation is required.

causal chain as a matter of law.[15] The Counties respond that the learned intermediary doctrine "is limited to personal injury, failure-to-warn cases," Opp. 34, but the reasoning of those cases is hardly so limited. If the "patient is expected to place primary reliance upon the physician's judgment," *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981), then it is hard to see how the Counties can establish the necessary "direct relation between the injury asserted and the injurious conduct alleged," *Cleveland v. JP Morgan Chase Bank, N.A.*, 2013-Ohio-1035, ¶ 15 (citation omitted). Under the learned intermediary doctrine, Pharmacy Defendants were not required to second-guess the prevailing standard of care.[16]

The Counties argue that doctors' wrongful prescribing cannot break the causal chain because intervening acts "do not constitute superseding causes if they were foreseeable." Opp. 32. In the Motion, Pharmacy Defendants cited an Ohio Supreme Court decision holding that unlawful conduct breaks the causal chain even if foreseeable. *See* Mot. 27. The Counties do not even bother to address it, instead pointing to a Sixth Circuit table decision (without acknowledging that it is unpublished). *See* Opp. 32 (citing *Harris v. St. Vincent Med. Ctr.*, 205 F.3d 1340 (6th Cir. 2000)). In any event, far from supporting the Counties, any focus on

[15] The Counties contend that this argument is precluded by four of this Court's prior decisions in the MDL. *See* Opp. 33, 35–36. The Motion already addressed two of those decisions—in the Track 1 proceeding and the Tribal Case Track. *See* Mot. 29 & n.13. Meanwhile, the decisions in *Cleveland Bakers* and *West Boca Medical Center* both turned on the finding that the decisions of prescribing doctors were tainted by alleged fraudulent marketing. *See* 2020 WL 1669655, at *6 (N.D. Ohio Apr. 3, 2020); 2020 WL 871539, at *16 (N.D. Ohio Feb. 21, 2020). The Counties allege no fraudulent marketing by Pharmacy Defendants.

[16] The Counties are wrong to assert that *Little v. Purdue Pharma, L.P.*, 227 F. Supp. 2d 838 (S.D. Ohio 2002), "declined to extend learned intermediary protection to pharmacies." Opp. 34. That decision did not actually address the question at all—instead leaving it for remand—and only found it "questionable" that a doctrine ordinarily applied to claims for "*strict liability*" would apply to "the *negligent* acts of pharmacies." 227 F. Supp. 2d at 850 (emphasis in original). As noted *supra* Part III, the Counties here have eschewed any claim for negligence and have pursued a per se absolute nuisance theory.

foreseeability just confirms that the learned intermediary doctrine breaks the causal chain. Under the learned intermediary doctrine, pharmacists and others in the supply chain may "reasonably assume that the physician will exercise his informed judgment in the patient's best interests." *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878–79 (Ohio 1991). As a matter of law, then, Pharmacy Defendants could not be expected to foresee that significant numbers of doctors would write prescriptions that lacked legitimate medical purpose.

Alternately, the Counties argue that doctors' prescribing cannot break the causal chain because it "occurred before Defendants' conduct in filling those prescriptions." Opp. 35. The problem with this argument is that the Counties' claims are not based on Pharmacy Defendants' "conduct in filling those prescriptions," but rather on their alleged failure to "adopt policies for analyzing and transmitting the information they had about red flags." *Id.* at 20–21. The Counties have not sought to pursue *any* claim based on the conduct of the pharmacists who actually filled the relevant prescriptions, and instead have focused on the adoption (or non-adoption) of corporate-level policies and procedures. Those policies and procedures were adopted before doctors wrote the particular prescriptions that were ultimately filled at Pharmacy Defendants' stores. The intervening conduct of those doctors breaks the causal chain as a matter of law.

CONCLUSION

The Counties' public nuisance claims against Pharmacy Defendants should be dismissed with prejudice.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on July 13, 2020.

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